



EUROPEAN PATENT APPLICATION

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Applicant: Lilly Industries Limited, Lilly House Hanover Square, London W1R 0PA (GB)

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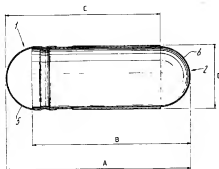
Inventor: Jones, Brian Elwood, 25 Richmond Road, Basingstoke Hampshire (GB)

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Representative: Hudson, Christopher Mark et al, Eri Wood Manor, Windlesham Surrey GU20 6PH (GB)

Two-part capsule.

There is described a two part capsule composed of rigid material readily soluble when ingested, preferably gelatin, which capsule comprises a cap and body, both of which are of cylindrical form and roundedly closed at one end and open at the other, the body being telescoped within the cap to form a closed container, the relative lengths of the body protrudes externally from the cap, the ratio of the length of the capsule to the diameter of the cap being in the range of from 2.5-3.5 to 1.



MEDICINAL FORMS

This invention relates to a two part capsule suitable for containing medicaments.

5 Two part capsules made of gelatin, or of some other similarly rigid film-forming material readily soluble in the body, are conventionally composed of a cylindrical open ended body portion closed by a cap which telescopes over the open end of the body. In the conventional capsule, the cap is approximately half as long as the body so that part of the latter's length is left exposed and the two parts, body and cap, can be drawn apart. Locking facilities, in the form of mutually engaging grooves or recesses in the cap and body are generally provided to avoid easy or accidental separation of the two

10 parts. These facilities, however, are frequently insufficient to prevent deliberate manual separation, and cases have been reported of such separation for the purpose of illicit tampering with the capsule contents. An object of the present invention is to provide a two part capsule, the construction of which

20 renders such manual separation impossible or more difficult.

Thus, the invention provides a two part capsule composed of rigid material readily soluble when ingested, preferably gelatin, which capsule comprises a cap and body, both of which are of cylindrical form and roundedly closed at

25 one end and open at the other, the body being telescoped within the cap to form a closed container, the relative lengths of the cap and body being such that only the closed rounded end of the

body protrudes externally from the cap, the ratio of the length of the capsule to the diameter of the cap being in the range of from 2.5-3.5 to 1.

By assembling the two parts of the capsule so that
5 only the closed rounded end of the body is exposed, insufficient cylindrical surface of the body is presented to enable the purchase necessary for manual separation of the two parts and by the suitable choice of the dimensions of cap and body, a tamper-resisting capsule is therefore obtained which, moreover,
10 retains the overall shape of conventional capsules that have gained acceptance from patients over a considerable period of time. The dimensions may also be such that machinery required in manufacture and filling need only be adapted to produce or handle the longer cap, since the body portion can be of standard
15 dimensions. Such production machinery can be of the usual kind in this art, with pins which are dipped into fluid gelatin, methyl cellulose, cellulose acetate or other suitable film material, the walls of the cap and body preferably being of equal thickness throughout.

20 The closed ends of the cap and body are preferably hemispherical but other suitable, generally rounded, shapes can also be employed. Thus, only the hemispherical portion of the body protrudes from the cap, so that no portion of the cylindrical part of the body is exposed to provide a grip by which the two
25 parts of the capsule can be drawn apart.

The cap and body are preferably of the same length so that the open end of the body portion abuts against the closed end of the cap. Other dimensions are possible, however,

provided that they allow the body to fit within the cap with only its end protruding. The ratio of the length to diameter of cap is preferably in the range of 2.1-2.6 to 1, for example from 2.3-2.45 to 1 and that of the body preferably in the
5 range of 2.2-2.7 to 1, for example from 2.4-2.6 to 1. It should be noted that when dimensions of capsule, cap and body are mentioned it is the external dimensions that are intended.

We have found that the ratio of cap length to the overall length of the capsule is preferably from 0.8-0.9 to 1,
10 such as from 0.82 or 0.85-0.9 to 1.

The invention is illustrated by way of example with reference to the accompanying Drawings, in which:

Figure 1 is a partial sectional view of one embodiment of a two part capsule according to the invention;

15 Figure 2 is a view of the cap of the capsule illustrated in Figure 1; and

Figure 3 is a similar view of the body of the capsule illustrated in Figure 1.

The capsule comprises a cap (1) and body (2) both
20 comprising a cylindrical portion (3 and 4 respectively) and a closed end portion (5 and 6 respectively) which is of hemispherical shape.

The cap is seen more clearly in Figure 2 and is of the type that includes a shallow annular shoulder (7) and
25 annular groove (8) towards its closed end (5). The cap can be tapered from its open end. The body (Figure 3) bears a corresponding annular groove (9) towards its open end (10), which is positioned so that when the capsule is assembled in

its final locked position and the two annular grooves (4 and 9) are engaged as seen in Figure 1, only the hemispherical closed end of the body (6) protrudes.

The shallow annular shoulder (7) allows the cap and
5 body to be loosely fitted together for storage or transport before the filling operation takes place and is positioned such that sufficient of the surface of the cylindrical portion is exposed to permit disengagement from the cap in preparation for the filling operation. Thus when assembling the cap and body
10 for transport before the filling operation, the open end of the body is slid within the cap as far as the annular shoulder (7) against which the open end (10) of the body lightly abuts and is held from further engagement. After disengagement and the filling operation, the cap and body can be engaged once more
15 and the body slid past the annular shoulder (7) so that the grooves (8 and 9) lock together.

With regard to the dimensions of the capsule, the overall external length (A) (Figure 1) of the assembled capsule and the external diameter of the cap (D) are in the ratio of
20 2.5 to 3.5 to 1 preferably in the range of 2.7 to 3.0, to 1. The length (B) of the body and the length (C) of the cap are substantially equal and the diameter of the body is such as to provide sliding engagement within the cap.

Examples of the dimensions of capsules according to
25 the invention are as follows:

	<u>Size*</u>	<u>Capsule</u>	<u>Body</u>		<u>Cap</u>		<u>Volume</u>
		mm	mm		mm		cc
		length	length	diameter	length	diameter**	
		(A)	(B)		(C)		
5	0	21.8	18.6	7.33	18.6	7.63	0.67
	1	19.5	16.5	6.62	16.5	6.90	0.48
	2	17.8	15.1	6.07	15.1	6.35	0.37
10	3	15.9	13.5	5.56	13.5	5.82	0.27
	4	14.5	12.3	5.06	12.3	5.32	0.20

* international size

** does not take into account taper

15 It will be appreciated that the invention has been described in relation to a preferred type of capsule, and many variations are possible. For example, the capsule cap and body need not possess the particular combination of grooves and shoulder as shown in the Drawings. Moreover, the length of

20 the cap need not be equal to that of the body provided it is long enough to provide sufficient cover for the body.

A preferred capsule of the invention is one in which the cap has an annular groove towards its closed end and the body has a corresponding annular groove near its open end, the

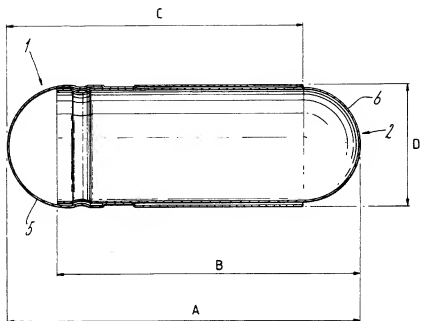
25 grooves being so positioned that in the assembled capsule they lock together and only the closed end of the body protrudes from the cap.

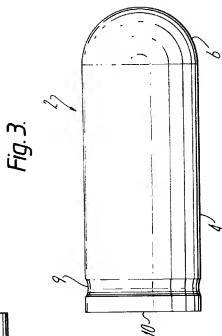
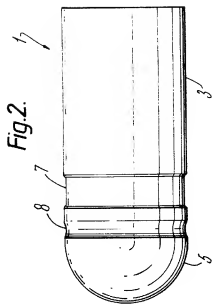
CLAIMS :

1. A two part capsule composed of rigid material readily soluble when ingested, preferably gelatin, which capsule
5 comprises a cap and body, both of which are of cylindrical form and roundedly closed at one end and open at the other, the body being telescoped within the cap to form a closed container, the relative lengths of the cap and body being such that only the closed rounded end of the body protrudes externally from the
10 cap, the ratio of the length of the capsule to the diameter of the cap being in the range of from 2.5-3.5 to 1.
2. A capsule according to claim 1 in which the closed ends of the cap and body are hemispherical.
3. A capsule according to either of claims 1 and 2 in
15 which the ratio of cap length to capsule length is from 0.8-0.9 to 1.

20

25

Fig.1.





DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
Y	FR-A-1 461 033 (R.P. SCHERER CORP.) * Figure 1; claims 1, 3, 4 *	1	A 61 J 3/07
A	---	2	
Y	DE-B-1 516 488 (ELI LILLY AND CO.) * Column 2, lines 53-62; figures 1-3 *	1	
A	---	1,2	
P,A	FR-A-1 153 998 (R.P. SCHERER CORP.) * Figure 3 *	1,2	

	EP-A-0 110 500 (WARNER-LAMBERT CO.) * Figures 1,2; claims 1, 2 *		

The present search report has been drawn up for all claims			
Place of search BERLIN		Date of completion of the search 14-12-1984	Examiner BARNY DE ROMANET P.M
CATEGORY OF CITED DOCUMENTS			
X	particularly relevant if taken alone		
Y	particularly relevant if combined with another document of the same category		
A	technological background		
O	non-written disclosure		
P	intermediate document		
T	theory or principle underlying the invention		
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